

REMARKS

This amendment is being submitted concurrently with a Request for Continued Examination under 37 CFR §1.114, entry of which are respectfully requested.

Applicants appreciate the Examiner's confirmation that the Terminal Disclaimer filed January 23, 2006 has been received and entered into the application.

Claims 39 and 44-47 are pending in the present application and currently stand rejected. The claims have been amended herein to more properly represent the notation of L-carnitine, support for which may be found in Table 2 of the instant specification. No new matter has been added.

Claim Rejections

Claims 39 and 44-47 are rejected under 35 USC §103(a) over Harper WO 00/44375 in view of Hamilton (US Patent No. 6,335,361 B1). This rejection is respectfully traversed.

According to the Federal Circuit, in order to establish a case of obviousness, three basic criteria must be met. There must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. There also must be a reasonable expectation of success and, finally, the prior art reference (or combined prior art references, as the case may be) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must be found in the prior art and not in the Applicants' disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See also MPEP 2143. This standard of review ("teaching, suggestion or motivation") is still deemed useful in an obviousness determination. KSR Int'l Co. v. Teleflex, Inc. No. 04-1350 (US Apr. 30, 2007).

In contrast to a case of obviousness under 35 USC §103, there may be the case where an invention is only “obvious-to-try” in view of the prior art, and this is not the proper standard for an obviousness rejection under the patent laws. (See generally, *In re O’Farrell*, 853 F.2d 894, 7 USPQ2d 1673 (Fed. Cir. 1988). According to the Federal Circuit,

[a]n “obvious-to-try” situation exists when a general disclosure may pique the scientist’s curiosity, such that further investigation might be done as a result of the disclosure, but the disclosure itself does not contain a sufficient teaching of how to obtain the desired result, or that the claimed result would be obtained if certain directions were pursued.

In re Eli Lilly & Co., 902 F.2d 943, 945 14 USPQ2d 1741 (Fed. Cir. 1990).

In this case, in the previous Office Action of June 6, 2006 and as maintained in the outstanding Office Action of February 12, 2007, the Examiner has argued that, with regard to the cited prior art,

Harper discloses using vitamin E and vitamin C to overcome the problem of oxidative stress in a cat and dog and to prevent or treat a disorder affected by oxidative stress. Disorders such as ageing and neurodegenerative disease are caused by oxidative stress and are treatable using the disclosed composition of Harper.

Office Action of February 12, 2007 at page 3.

The Examiner further argues that Hamilton discloses a method of treating cognition disorders associated with aging and for improving memory in older pets, the method involving administering an effective amount of a combination of carnitine and alpha-lipoic acid, preferably acetyl-L-carnitine and R-alpha-lipoic acid, and that the combination of antioxidants may be added to pet food for administration to animals such as dogs and cats. According to the Examiner, Hamilton discloses that the combination of antioxidants contributes to the improvement of mental acuity and inhibits age-related memory loss and provides improved memory in older subjects and also discloses that additional nutrients such as Vitamin E or C should be included as they are particularly

important in older subjects. The Examiner has also deemed Applicants' claimed dosage amounts obvious in light of the effective amounts disclosed in Hamilton and Harper (Office Action of June 16, 2006 at pages 3-4).

According to the Examiner, it would have been obvious to one of ordinary skill in the art to modify the method of Harper to specifically administer to the aged dog or cat Vitamin E, C in combination with L-carnitine and alpha-lipoic acid because one of ordinary skill in the art would reasonably expect the combination of these antioxidants to inhibit oxidative stress associated with aging. Also, according to the Examiner, since Hamilton discloses a method of improving memory in older pets and a method of treating age-related memory loss by administering carnitine and alpha-lipoic acid, one of ordinary skill in the art would reasonably expect the combination of antioxidants not only to inhibit oxidative stress associated with aging but also to counteract age-related memory loss and improve mental acuity in the aged dogs and cats of Harper.

In response, Applicants respectfully disagree with the Examiner's characterization of Harper, specifically that the cited reference teaches that Vitamin C and E affect *learning* in aged pets. The Examiner has stated in the outstanding office action that Harper teaches a treatment for ageing which is associated with oxidative stress and "the loss of learning ability is a cognitive deficit which occurs with ageing." Office Action of February 12, 2007 at page 3. Applicants respectfully submit, however, that the term "ageing" is nowhere defined in the cited reference and that such term can encompass a host of physical and mental conditions, some of which may be due to oxidative damage and some of which may not, a distinction which is not discussed in Harper.¹ Applicants respectfully submit that "ageing" can refer to a myriad of conditions, and Harper does not describe the effects of the claimed antioxidant cocktail on any age-related condition *per se*, and particularly, does not mention learning impairment as a condition that could be treated with the antioxidant cocktail described in Harper. As such, the cited reference

¹ For example, according to *Wikipedia*, "organismal ageing is generally characterized by the declining ability to respond to stress, increasing homeostatic imbalance and increased risk of disease."

clearly does not teach or suggest that the composition disclosed therein could be used in a method to inhibit the loss of learning ability or increase the learning ability of an aged companion pet as claimed in the instant invention.

Furthermore, Applicants respectfully submit that by disclosing a “dog or cat foodstuff...for use in the prevention or treatment of any disorder which has a component of oxidative stress” and then listing “ageing” among nearly a dozen other ailments, without providing any additional disclosure as to what physiological or pathological conditions associated with ageing might actually be treatable with the disclosed cocktail, Harper does not provide the necessary teaching required to render the instant invention obvious in combination with Hamilton. For example, in humans, loss of hearing, loss of normal bladder control and an increase in liver spots may all be associated with aging, yet Applicants doubt whether the cited reference actually provides sufficient disclosure to “treat” these conditions since it is unclear from the cited reference, which if any, may be due to oxidative damage. Indeed, *there is nothing in Harper that teaches that oxidative damage impairs learning ability in an aged animal, such that the antioxidant cocktail disclosed therein would be useful to treat such a condition.*

The Examiner has cited Hamilton as disclosing a method to treat cognition disorders associated with aging and to improve memory in older pets by administering a combination of antioxidants carnitine and alpha lipoic acid. In response, Applicants have argued that the cited reference teaches using carnitine and lipoic acid to discourage age-related memory loss and provide improved memory, but that memory and learning are distinct mental functions. In the outstanding action, the Examiner has argued the following in response:

While memory and learning are distinct mental functions, at the same time they are related and function hand in hand. With no memory there will be no retention of the learning. Therefore, whatever learned can be easily forgotten with lack of memory and, therefore, improved memory provides an increase in learning ability. Applicant’s claimed method steps are obvious in view of the prior art.

Office Action of February 12, 2007 at page 4.

In response, Applicants respectfully submit that the Examiner's position does not acknowledge the biochemical and physiological complexities and differences that distinguish the brain activities involved in learning and memory, the complete details of which have yet to be fully characterized in humans, let alone animals. For example, learning is the process by which new information is *acquired*, memory is the process by which knowledge is *retained*. One of ordinary skill in the art understands that the physiology of learning is complex, and can involve different parts of the brain, e.g., depending on whether learning is taking place by conscious acquisition of knowledge or whether what is being learned is a nonconscious learning of motor tasks. In addition to the actual molecular complexity of the process in general, studies indicate that there are actual gender differences in cognition, with men and women actually showing different aptitudes for math and verbal skills. In brief, studies to understand the exact biochemical and physiological processes involved in human learning are ongoing and the precise mechanisms involved have yet to be completely characterized. It goes without saying that the precise mechanisms of action involved in how animals acquire and process information have yet to be fully understood.

Similarly, the physiology of memory in humans (and animals) is no less complex and much remains to be understood with regard to the molecular and biochemical pathways involved in this brain function. Memory may be defined as a behavioral change caused by an experience and in this context, different types of memory have been identified. These include "declarative" memory and "procedural" memory, and refer to memories that may be available to our consciousness or unavailable to our consciousness, respectively. Studies with patients with impaired declarative memory but unimpaired procedural memory suggest that separate mechanisms for each type of memory exist and likely involve different areas of the brain. (Okano et al., PNA 97(23):12403-12404 (2000)).

Furthermore, memory may also be classified according to length of memory retention. In this context, scientists refer to sensory, short-term and long-term memory, and the three possess different characteristics, the exact details of which are beyond the scope of this discussion. The point is clear, however, that the biological events involved in memory formation in humans and animals are undoubtedly quite complex, and it is a fact that much research remains to be performed before the precise biochemical and physiological processes involved in memory are completely understood.

Given the very real scientific distinctions between learning and memory, taken together, Applicants respectfully submit that the combined teachings of Harper and Hamilton do not support a rejection of the claimed subject matter under 35 USC §103(a). The prior art simply does not disclose or suggest the claimed method for inhibiting the loss of learning ability or increasing the learning ability of an aged companion pet in need of such treatment comprising feeding the pet a mixture of antioxidants as disclosed in the instant invention, nor does it convey to those of ordinary skill in the art a reasonable expectation of success in doing so. More particularly, there is no suggestion in either of the cited references that the disclosed composition of antioxidants used to treat oxidative stress in Harper may be combined with the antioxidants disclosed to improve memory in Hamilton to achieve Applicants' claimed methods. Simply put, prior art teachings directed to oxidative stress and memory, without more, do not render obvious the methods of the instant invention which are directed to learning ability.

Although the Examiner has contended that learning and memory are "related and function hand in hand", the Examiner has provided no scientific evidence to substantiate this hypothesis. Indeed, the Applicants respectfully submit that the cited references contain insufficient teachings with regard to the actual physiological and biochemical mechanisms of action involved in the actual processes of learning and memory and thus one of skill in the art would not be motivated to combine the references to arrive at the cited invention to treat learning impairment nor would one be able to do so *with a reasonable expectation of success*. Indeed, as the Examiner concedes, "memory and learning are distinct mental functions"; as distinct mental functions, it follows that it is

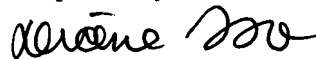
not unlikely that there are special and biochemically distinct molecular pathways involved in each process. The exact nature of each mechanism of action, however, remains to be characterized.

Since currently there are just too many scientific uncertainties regarding the actual physiological mechanisms of action involved in information acquisition and information retention, there is no evidence that the benefits of an antioxidant composition based on a combination of the cited references would have the same effects on learning as it might have on memory. While the Examiner argues that "products of identical compounds cannot have mutually exclusive properties", there is absolutely nothing in either of the cited references that teaches that the mechanisms of action of learning and memory are the same, nor is it appropriate based on the cited references to assume that such is the case. Without more, at best the combined teachings of Harper and Hamilton only render Applicants' invention *obvious to try*. Since this is not the proper standard for an obviousness rejection under 35 USC §103, Applicants respectfully request that this rejection be withdrawn.

Applicants believe that all of the Examiner's outstanding rejections in this case have been addressed herein and respectfully request reconsideration and allowance of all pending claims. If the Examiner believes that a telephone conference would expedite prosecution of this application, the Examiner is encouraged to telephone the undersigned at the number provided below. It is believed that no fee, other than the filing fee, is required. If any additional fees are required, please charge Deposit Account 50-2957.

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Respectfully submitted,



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